

Akin Gump

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March 31, 2016

National Freedom of Information Officer
U.S. Environmental Protection Agency
1301 Constitution Avenue, NW
Room 6416 West
Washington, D.C. 20004

Re: Freedom of Information Act Request for Records Pertaining to EPA's New
Chemical Program Policy and Implementation

Dear EPA FOIA Officer:

This is a request under the Freedom of Information Act (FOIA), 5 U.S.C. § 552(a), as implemented by the U.S. Environmental Protection Agency (USEPA) at 40 C.F.R. Part 2, Subpart A et seq. by Akin Gump Strauss Hauer & Feld, LLP. This FOIA Request is separate and independent from the FOIA request submitted March 16, 2016 ("March 16 Request") and nothing in this submission should be interpreted to affect the Agency's obligation to meet its statutory response deadlines with respect to the previously submitted March 16 Request.

Pursuant to the Freedom of Information Act, 5 U.S.C. § 552(a), please provide all Documents and Correspondence¹ responsive to the following requests:

1. With respect to the Toxic Substances Control Act (TSCA) and its regulations, please provide copies of any proposed or final, unilateral or voluntary TSCA section 5(e) Consent Order (Order), TSCA section 5(a) Significant New Use Rule (SNUR), or other rule, order or binding opinion issued pursuant to 15 U.S.C. 2604-2605 requiring compliance with one or more of the following restrictions as a condition for a person to manufacture, import, process or distribute in commerce a chemical substance in the United States:

¹ For the purposes of this request, the term "Documents and Correspondence" means any record, electronically stored information, or other written material, including books, research papers, treatises, publications, memos, reports, emails, notes (handwritten and electronic), other written communications, voicemails, drawings, graphs, charts, sound recordings, images, and other data or data compilations. The terms "includes" or "including" mean "including, but not limited to."

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- a) Restricting the container size of a chemical substance or mixture to a minimum volume of 10 gallons (or its equivalent weight) or greater.
 - b) Restricting the sale or distribution of any product containing a chemical substance into a “consumer” use (as defined in 40 CFR 721.3), including for use in “consumer products” (as defined in 40 CFR 721.3) or “commercial use” (as defined in 40 CFR 721.3) when the “saleable goods or service” could introduce the chemical substance into a “consumer” setting (as defined in 40 CFR 721.3).
 - c) Mandating as an enforceable requirement on the manufacturer, importer, formulator or other party the responsibility to conduct and submit to EPA results of glove permeability testing on any “new formulation” which is defined as any formulation wherein the concentration of any component is changed (increased or decreased) by 1% or greater from a previously tested formulation prior to any manufacture, import or distribution in commerce of the formulation.
 - d) Restricting the concentration of a chemical substance to a maximum concentration in formulated products for industrial uses.
 - e) Restricting the concentration of a chemical substance to a maximum concentration in a formulated product based on toxicology data of a different chemical substance for which such restrictions have not been imposed for similar end uses.
 - f) Mandating a written agreement with a person to follow one or more restrictions on minimum container size, uses (consumer and commercial), new glove testing and concentration limits for distribution.
- 2. Please provide a copy of or cite to any EPA regulation or policy recommending or requiring regulated entities to maintain hazardous materials in containers with a capacity of 40 gallons or greater, without regard to the quantity required for the regulated process.
 - 3. Please provide any report, study, analysis or opinion issued by or on behalf of the EPA or provided to the EPA by any Federal Agency, submitter of a TSCA section 5 Premanufacture Notice, or public commenter that assesses:
 - a) The policy, legal or scientific justification for imposing restrictions on chemical substances under review by the EPA’s New Chemicals Program pursuant to

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- Section 5 of TSCA subject that are not required for existing chemicals (i.e., the so-called “New Chemical Bias”²);
- b) The impacts of such restrictions on competition of the U.S. chemical industry in general and specifically on the development and availability of reduced-risk alternatives to existing chemical substances regulated (i.e., grandfathered) under section 6 of TSCA in particular;
 - c) The specific level of risk that the EPA considers to be reasonable when regulating a new chemical or new use of a chemical under TSCA section 5 where EPA has not regulated similar chemicals or uses with greater known risks.
4. Copies of each of the sample EPA Section 5(e) “boiler plate” Consent Orders previously available on EPA’s “Index of Boilerplates for Orders - New Chemicals Program” page or other similar pages between July 2014 and December 31, 2015,³ prior to their removal from the EPA’s website in January 2016.⁴ Such documents shall include the following document titles:
- a. Pollution Prevention Plan;
 - b. Hybrid Risk/Exposure-Based Health/Eco;
 - c. Risk-Based Human Health w/ NCELS;
 - d. Risk-Based Human Health Dermal Only;
 - e. Risk-Based Ecotoxicity;
 - f. Exposure-Based Human Health;
 - g. Exposure-Based Ecotoxicity;

² See, e.g., EPA, *EPA Journal*, Volume 10, Number 5 (June 1984) at 5 (“We are also conscious of introducing a “new chemical bias” in the system.”); EPA, *New Chemicals Program*, EPA743-F-95-001 (May 1995) at 12 (“Why does EPA regulate a new chemical and not a similar chemical already on the market? This issue is sometimes referred to as a “new chemical bias.”).

³ These sample “Boilerplate” orders may have been posted at multiple web addresses. At least one such address, <http://www.epa.gov/opptintr/newchemicals/pubs/boilerpl.htm>, but others addresses may have been used during the requested period.

⁴ See <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/new-chemicals-exposure-limits> (currently limited to one sample order, *Section 5(e) Consent Order NCEL insert* (PDF)(33 pp, 163 K)).

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- h. Exposure-Based Hybrid;
- i. Triggered Glove Testing;
- j. Section 5(e) Contract Manufacturer Orders;
- k. Contract Manufacturer: Insert for Company's Order;
- l. Contract Manufacturer: Risk-Based Eco;
- m. Contract Manufacturer: Exposure-Based Eco;
- n. Contract Manufacturer: Risk-Based Health; and
- o. Contract Manufacturer: Exposure-Based Health.

In accordance with the applicable regulations, we will pay a fee for the reasonable costs associated with producing the documents and other information above. We kindly request that the EPA notify us in advance if it anticipates the fee for this request will exceed \$1,000.00.

Thank you very much for your consideration.

Sincerely,

A handwritten signature in black ink, appearing to read "Charles L. Franklin", with a long horizontal flourish extending to the right.

Charles L. Franklin